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“I Need Your Organ and All of the Details about Your Life”-Living Organ Donation: The Privacy of the Organ Donor vs. The Right to Information of an Organ Recipient

Brian Frankoski

Seton Hall Law

J.D. Candidate, May 2014

Ted is a forty-three-year-old white male who has had no significant health issues in his life. He is, and has been, married to forty-five-year-old Sarah for ten years, and while they have had some issues, Ted has always been there for her. The couple lives together in Chicago, Illinois. Sarah is a nurse that, unfortunately, has not had the same luck as her husband when it comes to her overall health. She was diagnosed with diabetes when she was in her late adolescence. For nearly twenty-five years, Sarah was able to manage the disease with no serious side effects to her body. Once in her mid-thirties, however, she began developing kidney problems and was diagnosed with chronic kidney disease (CKD). Slowly, her kidneys stopped performing the functions they once had.

Recently, Sarah's CKD developed into end-stage renal disease (ERSD) and she is now in need of either dialysis or a kidney transplant. Sarah starts on dialysis, but places her name on the kidney transplant recipient waitlist as well. While the dialysis is her saving grace for some time, it begins to not work as effectively. Sarah is told by her doctors to explore options within her immediate family and close friends to see if any of them are a match for a kidney transplant and willing to participate in the procedure. While Sarah feels uncomfortable asking for such a life-altering request, she knows it is her best bet.

Ted goes with his wife to the transplant wing of Northwestern University Medical Center to get preliminary blood work done to find out if he is a match. A few days later, the hospital calls and tells Ted that his kidney is compatible. Though excited to tell his wife, the doctor suggests that Ted comes to the hospital to discuss the donation process privately.

Once at the hospital, Ted meets with the transplant surgeon who informs him that while his blood is compatible with his wife's, there are many other steps that need to be done before

the transplant can take place. The doctor hands Ted some forms and informative pamphlets which illustrate the process. He tells Ted to take the materials home, read them over, and get back to him as soon as he is ready with any questions or to make a decision to carry on with the process.

Upon reading the information he was given by the doctor, Ted is taken aback by the number of blood tests, x-rays, and overall lifestyle restrictions that will occur as a result of him being a donor. His eyes scroll through the numerous pages of the paperwork, where, at some point, he comes across one section titled “Risk Behaviors”. The section posed fourteen questions pertaining to his behavioral history, including, but not limited to, drug use, sexual activity, and exposure to HIV. It explains beneath the list of inquires that participation in any of the named activities would result in his organ being designated an “increased risk”.¹ Ted reads on and learns that the designation means that his organ requires “special informed consent” from the organ recipient because it carries a greater likelihood of carrying transmissible, blood borne pathogens, that may not have been present during the screening process, but could arise prior to transplantation.² This period of time is referred to as the “window period” for infection.³ The document further explains that in order for the transplant to occur at this hospital, Northwestern Medical must disclose to the recipient the behavior associated with the increased risk status of the organ. Ted thinks back a year and a half when his marriage was a bit shaky and he had made

¹ Matthew J. Kuehnert, Ingi Lee, Debbie L. Seem, Craig A. Umscheid, *PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus Transmission Through Organ Transplantation*, 128 PUB.HEALTH REP. 247, 251 (2013), available at <http://www.publichealthreports.org/issueopen.cfm?articleID=2975>.

² ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP’T OF HEALTH & HUMAN SERV., POLICY 4.2- REQUIREMENTS FOR INFORMED CONSENT REGARDING RISK OF TRANSMISSIBLE DISEASE, at 4-1 (2013), available at http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_16.pdf.

³ See, Kuehnert, *supra* note 1, at 260; See also, N. Beauvais, J. Franklin, E.J. Gordon J. Hanneman, M.G. Ison, S. Jensen G. McNatt, D. Penrod, L. Sherman, N. Theodoropoulos, *The Challenge of Informed Consent for Increased Risk Living Donation and Transplantation*, 11 AM. J. OF TRANSPLANTATION 2569, 2570 (2011), available at <http://onlinelibrary.wiley.com/doi/10.1111/j.1600-6143.2011.03814.x/pdf>.

the mistake of cheating on his wife. Ted had used the services of a prostitute on multiple occasions, though had not done so for the past year. The Northwestern risk behavior form states that paying for sex at any point in the past three years is a risk behavior which will result in an increased risk designation of the organ, and thus require special informed consent from the recipient and disclosure of the risk behavior associated with it.⁴

Ted now faces a startling dilemma. His wife, Sarah, has been put on the kidney recipient waitlist, with nearly 80,000 individuals, where she faces the grim reality that an organ match and transplant could take five years, longer, or may not come at all.⁵ Sarah is also seeking kidneys from other sources. Ted can, of course, choose to agree to the disclosure, however, the nature of their relationship being the prime motivation for donation, divulging this information could hamper or prevent donation and ruin his marriage.

These two interests, the right of the recipient to be fully informed when making a medical decision and the privacy rights of the organ donor, are at odds and formulate the question herein addressed. The scenario illustrated above is what could occur if legal informed consent in living organ transplantation requires every transplant center to disclose to the recipient the behavior associated with an increased risk organ. While the relationship between the donor and recipient is not always a spousal one, it remains that the revelation of private information can still hamper bonds and expose the donor to stigmatization.⁶ Additionally consider the coercive effect on the donor's decision to donate of a policy which will not allow a donation to occur unless one agrees to allow the disclosure of private information.⁷ A donor will feel compelled to reveal private

⁴ See Kuehnert, *supra* note 1, at 251.

⁵ United Network for Organ Sharing, www.unos.org (last visited December 1, 2013).

⁶ See Beauvais, *supra* note 3, at 2571, 2572.

⁷ See Beauvais, *supra* note 3, at 2571; *But cf.*, Richard H. Dees, *Transparent Vessels?: What Organ Donors Should be Allowed to Know About Their Recipients*, 41 J. LAW, MEDICINE AND ETHICS 323, 327 (2013) (stating that were a

information because someone's life is at stake.⁸ This conflicts with the voluntary aspect of donation which promotes participation in the process for the purpose of doing a good deed.⁹

The argument, in part, for disclosure is that the information is material and necessary for organ recipients to make a "fully informed", autonomous decision.¹⁰ The recipient should, after all, feel absolutely comfortable with the decision to accept an organ. However the donors have privacy rights and expectations, and these rights are afforded great protections as to their personal medical information.¹¹ The legal issue then becomes, *Does the organ recipient have a legal right to the personal information of the living organ donor?*

I am not convinced that the need for such information outweighs the importance of protecting the individual privacy of the organ donor. Therefore, I submit that 1) an organ recipient's interest in the information is not paramount to the organ donor's privacy rights, and 2) that the organ recipient is *fully informed* under the law even while withholding the risk behavior associated with the organ donor.

A number of legal and ethical concerns arise in the context of live-organ donation, each worthy of being addressed. I will begin my analysis by briefly introducing the Organ Procurement and Transplantation Network (OPTN), its functions, and the goals which dictate its daily activities. By understanding the many entities and individuals involved in the transplantation process, one will better grasp the mission of the OPTN, the justification for its current governing rules, and the legal analysis which follows.

donor permitted to know the recipients private information, the recipient would feel compelled to disclose), available at <http://onlinelibrary.wiley.com/doi/10.1111/jlme.12023/pdf>.

⁸ See Beauvais, *supra* note 3, at 2571, 2572.

⁹ See Dees, *supra* note 6, at 324.

¹⁰ See Gordon ET AL., *supra* note 3, at 2570.

¹¹ *Id.*

Following this introduction, the second portion of the paper will outline and analyze the current rules and policies of the OPTN and CMS which govern this legal issue. This will include policies pertaining to informing and evaluating the potential living donor, protecting the donors' and recipients' rights, and the information which is required to obtain the informed consent of a potential organ recipient. It will be seen that great leeway is given to the respective transplant programs and surgeons in carrying out their interpretations of the rules.¹² Dual regulation of the transplant community by the OPTN and CMS has led to transplant programs being uncertain in how to develop in-house procedures that meet the requirements of both and how to address overlaps in rule-making.¹³

In part three, I will address the role the common law has played in the development of informed consent. Pertinent to this section is grasping the concepts and rules of informed consent that developed through case law. Rules will be taken from the common law and applied to the context of the living donor issue. The goal of this section is to consider the rules set forth by the OPTN and CMS and determine whether the information supplied to transplant candidates would satisfy the informed consent requirements dictated at common law.

Lastly, I will introduce an alternative to requiring risk behavior disclosure. This section will describe a current program that is being used by the OPTN which could allow donors to aid in providing an organ to the recipient whom they know, while not having to reveal any risk behaviors.

¹² See Gordon ET AL., *supra* note 3, at 2571.

¹³ *Id.*

Part I-THE ORGAN PROCURMENT TRANSPLANT NETWORK (OPTN)

As the plausibility of organ transplantation grew in America, so did the interest and recognition of its potential by the general public, the healthcare community, and government officials.¹⁴ A federal initiative was undertaken to create an organization that would establish a network of organ transplantation entities to be governed under uniform policies, allowing organ procurement to grow expeditiously throughout the country.¹⁵ Of particular concern, was the need to create a database which would identify organ donors and recipients, as well as arrange for the acquisition, preservation, and procurement of the harvested organs.¹⁶ The National Organ Transplant Act of 1984 created the Organ Procurement and Transplantation Network (OPTN) and ordered the Secretary of Health and Human Services to promulgate any and all rules necessary to carry out its mission.¹⁷ In 1986, the Secretary contracted a non-profit, administrative agency, the United Network for Organ Sharing (UNOS), to carry out the OPTN mission and functions.¹⁸ Presently, UNOS remains the entity which manages the OPTN.¹⁹

UNOS and the OPTN are responsible for enabling and maintaining an organized and efficient network capable of, amongst many other duties, developing and implementing policies to ensure the equitable allocation of available organs, keeping up with scientific and technological developments in the transplant community, and detecting weaknesses in the organ

¹⁴ DAVID L. WEIMER, MEDICAL GOVERNANCE: VALUES, EXPERTISE, AND INTERESTS IN ORGAN TRANSPLANTATION 44-46 (2010).

¹⁵ *Id.* at 46-47.

¹⁶ *Id.*

¹⁷ National Organ Transplant Act, Pub. L. No. 98-507, §372(a), 98 Stat. 2339, 2344 (1984), *available at* <http://history.nih.gov/research/downloads/PL98-507.pdf>.

¹⁸ WEIMER, *supra* note 9, at 47.

¹⁹ *Id.*

network by gathering and analyzing data.²⁰ The entities and individuals that are members of the organization include transplant hospitals, organ procurement organizations, physicians in the transplant community, transplant coordinators, histocompatibility labs, as well as individuals who have participated in the donation process directly or indirectly.²¹ The organization has since been responsible for over 500,000 successful living and deceased donor transplantations nationwide since 1987, saving numerous lives and playing a key role in the scientific development of the logistically and medically complex procedure.²²

Lastly, the enforceable powers granted to the OPTN through legislation are worthy of addressing. The OPTN does have the authority to discipline its member organizations for failing to abide by OPTN policies and bylaws.²³ This is done through removal of voting rights, dismissal from board representation, and administering and monitoring a strict compliance program that the violating member must follow to be placed back in good standing with the organization.²⁴ However, the OPTN cannot suspend or permanently remove the transplant privileges of the member for violations.²⁵ This can only be accomplished through recommendations made to the Secretary of HHS who, ultimately, decides whether or not to take such action based on the information she receives and the severity of the offense.²⁶ Nonetheless, the ability of the OPTN to publicly dispense the violative conduct of its members serves as a strong tool to promote enforcement of OPTN policies.

²⁰ National Organ Transplant Act §372; *See also*, UNITED NETWORK FOR ORGAN SHARING, *ARTICLES OF INCORPORATION* (June 2009), *available at* http://www.unos.org/docs/UNOS_ArticlesOfIncorporation_062309.pdf.

²¹ 42 C.F.R. §121.3(b) (2012).

²² UNITED NETWORK FOR ORGAN SHARING, 2012 ANNUAL REPORT (2012), *available at* <http://www.unos.org/docs/AnnualReport2012.pdf>.

²³ WEIMER, *supra* note 14, at 53.

²⁴ *Id.*

²⁵ *Id.*

²⁶ 42 C.F.R. §121.10(c)(1),(2), (i)-(iv).

The bulk of the enforcement of OPTN policies and discipline comes primarily from the Center for Medicare and Medicaid Services. CMS requires that all hospitals performing transplants that participate in Medicare be OPTN members and adhere to the rules and policies promulgated by the OPTN and approved by the Secretary of HHS.²⁷

Part II- The Policies of the OPTN

Informing the Donor and Recipient: Initial Steps

The process of obtaining fully informed consent from both the donor and recipient begins at the first appointment and, in many ways, continues throughout the transplant process.²⁸ The physicians involved are devoted and encouraged to address the importance of maintaining a healthy donor-recipient relationship.²⁹ OPTN policies obligate transplant hospitals to provide educational lectures and tutorials to the donor so that he may comprehend the many emotional, physical, and mental obstacles that could, and likely will, arise.³⁰ In doing so, it allows each individual to grasp the realities of the surgery and post-surgery life and, perhaps, defunct any notions of a risk-free, unchallenging experience.³¹ The functionality of this step in the informed consent process is to address significant concerns early in the donation so that no surprises which may affect the donor-recipient relationship arise later on.³²

²⁷ 42 C.F.R. §482.72 (2012).

²⁸ See Dees, *supra* note 6, *passim*.

²⁹ *Id.* at 328, 330.

³⁰ ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP'T OF HEALTH & HUMAN SERV., POLICY 12.0: 12.2 (a)-(1): INFORMED CONSENT OF LIVING KIDNEY DONORS, at 12-1 to 12-3, *available at* http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_172.pdf

³¹ See Dees, *supra* note 6, at 325.

³² See, e.g., ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP'T OF HEALTH AND HUMAN SERV., *POLICY 12.2-INFORMED CONSENT OF LIVING DONORS: INTRODUCTION*, at 12-1 (2013), *available at* http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_172.pdf; See also Michael M. Abecassis, John Friedewald, Elisa J. Gordon, Michael G. Ison, Daniel P. Ladner, Elizabeth Reddy, *Kidney Transplant Candidates' Understanding of Increased Risk Donor Kidneys: A Qualitative Study*, 26 CLINICAL TRANSPLANTATION 359 (2012), *available at* <http://onlinelibrary.wiley.com/doi/10.1111/j.1399-0012.2011.01536.x/full>.

Independent Donor Advocates (IDAs)

While the gift of an organ is considered an altruistic one, it still remains that each party to the transplantation procedure has interests and rights which must be protected.³³ The donor, through OPTN policy and CMS rules, receives this protection, in part, in the form of an “Independent Donor Advocate”(IDA).³⁴ OPTN and CMS policy require that all of its transplant hospitals provide the prospective donor with an IDA.³⁵ The IDA serves to promote the best interests of the donors, promote their rights, and assist the donors in obtaining and understanding information as it pertains to each step of the transplantation process.³⁶ This would include protecting the donors’ privacy as it pertains to the disclosure of risk behaviors learned of in the evaluation process.³⁷ The IDA serves only the donor, and has no authority in final treatment decisions or in seeing the transplant through for the benefit of the recipient.³⁸

Consider the scenario in the introduction. Ted, the donor, could certainly voice his concerns to the IDA that is assigned to him over the policy of disclosing risk behaviors, but little could be done to address these concerns which would result in non-disclosure and donation, at least at this hospital. The IDA would likely advise Ted that at no point should he be willing to disclose this information unless he is entirely ready and is doing so voluntarily and for the appropriate reasons.³⁹ The IDA would also protect Ted from any improper inducement or

³³ See Dees, *supra* note 6, *passim*.

³⁴ 42 C.F.R. 482.98(d) (2012); ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP’T OF HEALTH AND HUMAN SERV., POLICY 12.4: 12.4.1-DEPENDENT DONOR ADVOCATES, at 12-8 to 12-9 (2013), *available at* http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_172.pdf.

³⁵ *Id.*

³⁶ *Id.*; See also Dees, *supra* note 6, at 323, 324.

³⁷ See Dees, *supra* note 6, at 323, 324.

³⁸ 42 C.F.R. 482.98(d)(3)(i)-(iii) (2012); ORGAN PROCUREMENT TRANSPLANT NETWORK, *supra* note 33.

³⁹ ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP’T OF HEALTH AND HUMAN SERV., POLICY 12.0:12.3.4 (L)-EXCLUSION CRITERIA, at 12-8 (2013), *available at* http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_172.pdf; See also Beauvais, *supra* note 3, at 2571-572; See also Dee, *supra* note 6, at 328.

persuasive tactics of the transplant hospital in the event that they attempt to coerce him into agreeing to disclose.⁴⁰

Transplant Teams-Separate but Equal

Concomitant to the protections offered the donor through the IDA, are those afforded the recipient by his/her “transplant team”.⁴¹ Each party to the transplant has its own team of doctors, referred to as the “transplant team”, that evaluate and prepare their respective patient for the procedure.⁴² The goals of the recipient transplant team are to ensure the likely outcome of the transplant is a promising one.⁴³ In carrying out this goal, the team is to protect the interests of the recipient and take all ethical measures needed to guarantee the donor organ is medically suitable.⁴⁴ The determination over what information is material to the decision-making process is left to the medical judgment of the respective transplant program.⁴⁵ Some organ recipient advocates argue that this determination should be subjective one, and the materiality of any information should be left to the organ recipient.⁴⁶ Researches have also found an overload of information can actually harm rational decision-making, stating, “more information may not always benefit the patient, especially in situations where the medical decision is complex, when there are many options, when the decision is acute and time-sensitive and when there is great uncertainty.”⁴⁷ Another study suggests that providing the information and obtaining specific informed consent actually results in higher utilization of increased risk organs, though this

⁴⁰ Patient’s Rights 42 C.F.R. 482.13(e) (2012); *See also* Dees, *supra* note 6, at 326.

⁴¹ *See* Dees, *supra* note 6, at 324, 325.

⁴² *Id.*

⁴³ *Id.* at 325.

⁴⁴ *Id.*

⁴⁵ ORGAN PROCUREMENT TRANSPLANT NETWORK, *supra* note 2; *See also*, Dees, *supra* note 3, at 326.

⁴⁶ *See* Dees, *supra* note 6, at 329; *Contra, id.* at 328 (standing for proposition that allowing a patient to determine which information is material will place too heavy a burden on the patient).

⁴⁷ D. W. Hanto, K. Ladin, *Informed Consent and Living Kidney Donation: More (Information) Is Not Always Better*, 11 AM. J. TRANSPLANTATION 2547, 2548 (2011) .

pertains to transplants in the deceased donor context.⁴⁸ Clearly, there is a lack of uniformity as to what is the appropriate amount of information to divulge to a transplant candidate.⁴⁹ However, transplant programs remain free to determine their own policies as it pertains to the information they think should be disclosed to the potential recipient so long as the process remains in line with the vague regulatory authorities.⁵⁰

OPTN Policy 12.0-Living Donation

The OPTN has policies specific to each and every possible transplant available.⁵¹ *OPTN Policy 12.0-Living Donation* generally dictates the requirements of its members as it pertains to living donations.⁵² The terms of this section expressly provide for the informing requirements owed to the donor by the hospital, the medical and psychological tests to be performed on the donor, and social and behavioral evaluations which must be completed prior to transplant approval.⁵³ Though some of the rules within this section apply to all living donors, most pertain specifically to living kidney donation.⁵⁴ The language of the policies in this section are quite general and do not limit the transplant programs' ability to apply them, but instead, serve as a guideline with some articulated requirements.⁵⁵

⁴⁸ C. Hanrahan, L.M. Kucirka, R.A. Montgomery, R. Namuyinga, D.L. Segev, *Formal Policies and Special Informed Consent Are Associated with Higher Provider Utilization of CDC High-Risk Donor Organs*, 9 AM. J. TRANSPLANTATION 629, 634 (2009), available at <http://onlinelibrary.wiley.com/doi/10.1111/j.1600-6143.2008.02523.x/pdf>.

⁴⁹ *Id.*

⁵⁰ See Kuhnert, *supra* note 3, at 2570.

⁵¹ See, ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP'T OF HEALTH AND HUMAN SERV., BYLAWS (2013), available at http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Bylaws.pdf#nameddest=Appendix_F.

⁵² ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP'T OF HEALTH AND HUMAN SERV., POLICY 12.0-LIVING DONATION (2013), available at http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_172.pdf.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

The expressed informing obligations of the transplant hospital, in the context of a living kidney transplant, require it to disclose to the organ donor that the hospital will take “all reasonable measures to protect the confidentiality of the donor and recipient”.⁵⁶ No definition is provided to define “reasonable measures”, which seems to leave the transplant hospital to use its best judgment.⁵⁷ OPTN policy stipulates the transplant hospitals must inform the donor that all health information that is obtained during their evaluation “will be subject to the same regulations as all records and could reveal conditions that the transplant center must report to local, state, or federal public health authorities.”⁵⁸ However, it does so without referencing the specific regulations that “all records” are subjected to, perhaps leaving the donor not as informed as she could be. The later part of the policy refers to mandatory reporting requirements which obligate transplant hospitals to disclose patient information, without authorization, for public health purposes.⁵⁹

Conspicuously missing from the informed donor policies is any expressed requirement that the hospital obtain the donors consent in order to reveal health risks to the potential recipient. The lack of clarity only frustrates the goal of achieving uniformity in hospital policies and in fully informing donors as to their privacy protections. A survey and study pertaining to disclosure of risk behaviors revealed many transplant surgeons do decide to reveal the risk behavior associated with an increased risk donor, at least in the deceased donor context.⁶⁰ The study showed that 77% of 422 surgeons surveyed did reveal both the high risk status of the organ

⁵⁶ ORGAN PROCUREMENT TRANSPLANT NETWORK, *supra* note 51, at 12-1, POLICY 12.2(c).

⁵⁷ *Id.*

⁵⁸ *Id.* at 12-3, POLICY 12.2(j).

⁵⁹ ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP’T OF HEALTH AND HUMAN SERV., POLICY 7.0-DATA SUBMISSION REQUIREMENTS (2013), *available at* http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_23.pdf.

⁶⁰ *See* Hanrahan, *supra* note 47, at 631.

and the behavior which lead to the designation.⁶¹ While privacy is not as much of a concern in the deceased donor contacts, the study may be read to mean that transplant surgeons do find the information relevant.

The Public Health Service (PHS) provides transplant programs with the list of risk behaviors that are used to designate organs as increased risk.⁶² OPTN policy requires transplant programs to use the PHS risk assessment guideline when conducting an evaluation of a donor in regards to questions pertaining to the donor's past social and behavioral history.⁶³ However, this evaluation is not limited to the questions set forth in the PHS guideline, allowing a transplant hospital to add to the list.⁶⁴ These questions are designed to assess the risk of transmission for HIV, HBV, and HCV only.⁶⁵ PHS guidelines limit disclosure to behaviors participated in during the preceding 12 months.⁶⁶ However, this is the minimum required time frame. Transplant programs can adjust this time period as they deem fit. An affirmative answer to any of the questions results in the increased risk designation of the organ.⁶⁷ The behaviors indicated by PHS to be included in the evaluation are the following:

⁶¹ *See id.* at 632.

⁶² *See* Kuehnert, *supra* note 1, at 251.

⁶³ ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP'T OF HEALTH AND HUMAN SERV., OPTN POLICIES: REWRITE PROJECT-15.3 IDENTIFICATION OF TRANSMISSIBLE DISEASES, at 192 (2013) (rewrite project was undertaken in 2013 by the OPTN to better explain the policies to transplant programs...though not an official document, it serves to aid programs in writing policies), *available at* http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies_PC_08-2013.pdf#nameddest=Policy15.

⁶⁴ *Id.*

⁶⁵ Kuehnert, *supra* note 1, at 247.

⁶⁶ *Id.* at 251.

⁶⁷ *Id.*

BEHAVIORS PARTICIPATED IN DURING THE PREVIOUS 12 MONTHS

- Sex with anyone known to be infected with HIV, HBV, or HCV
- Men who have had sex with other men
- Women who have had sex with men that have had sex with other men in the preceding 12 months
- People who have had sex in exchange for money or drugs
- People who have had sex with a person who had sex in exchange for money or drugs in the preceding 12 months
- People who have injected drugs through intravenous, intramuscular, or subcutaneous route for non-medical reasons
- People who have had sex with someone who has injected drugs through intravenous, intramuscular, or subcutaneous route for non-medical reasons in the preceding 12 months
- People who have been in lock-up, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours
- People newly diagnosed with, or have been treated for, syphilis, gonorrhea, Chlamydia, or genital ulcers
- People who have been on hemodialysis

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In 2011, approximately 7.7% of all transplants came from increased risk donors.⁶⁹ According to the PHS guideline, from January 1, 2005 through December 31, 2011, there were 134 reported transmissions of infectious diseases in recipients that were donor-derived.⁷⁰ Of those 134, 104 came between 2008 and 2011.⁷¹ And of those 104, ten infections were of HCV, four were HBV, and one was HIV (the infections which the risk behaviors questionnaire are designed to address).⁷² The last *living* donor infection transmission occurred in 2009, where a man who had engaged in a risk behavior (sex with another male) transmitted HIV.⁷³ However, stored specimens revealed that HIV was present in a pre-testing stage, though it may have gone

⁶⁸ *Id.*

⁶⁹ Abecassis, *supra* note 37, at 359.

⁷⁰ Kuehnert, *supra* note 1, at 259.

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.* at 260, 261.

overlooked.⁷⁴ Much of the success in preventing transmission can be attributed to pre-testing procedures that can limit window periods for infections to as low as five days.⁷⁵ This supports studies which indicate that remaining on the wait list is a far more dangerous to health than accepting a high risk organ.⁷⁶

The guideline points to two major deficiencies in risk behavior policy, assessment, and guidance. Firstly, there is little data linking risk behaviors to actual transmissions of infections.⁷⁷ It states that testing recipients who receive increased risk organs is not required by OPTN policy and it is not the standard procedure of transplant hospitals.⁷⁸ The guideline goes on to indicate that much information is needed before any certainty can be concluded about risk behaviors and their likely effect on rates of transmission.⁷⁹ Secondly, and key to this discussion, is that the guideline points out major deficiencies in reliable research and the “paucity” of data regarding correlation between the listed risk behaviors and the likelihood the donor has a transmissible infection.⁸⁰ A large portion of the guideline is dedicated to discerning what evidence the originators of the initial risk behavior guideline, released in 1994 and not substantially changed since, used in determining that there was a correlation between certain behaviors and infections of HIV, HCV, and HBV in those individuals.⁸¹ The authors found that low-quality evidence was used to create the list, and that, presently, for many of the behaviors, the jury is still out on rates of infection associated with the conduct.⁸²

⁷⁴ *Id.*

⁷⁵ *Id.* at 260.

⁷⁶ *Id.* at 294, 295.

⁷⁷ *Id.* at 272-295

⁷⁸ *Id.* at 296.

⁷⁹ *Id.* at 296.

⁸⁰ *See Id.* at 272-290 (summary of evidence used to evaluate risk factors).

⁸¹ *Id.*

⁸² *Id.* at 290.

The guideline recommends, going forward, that national data be collected on HIV, HCV, and HBV transmission rates based on donor and recipient testing to better inform policy decisions and screening requirements.⁸³ It is also suggested that data be collected on behavioral and non-behavioral risk factors associated with increased incidence and prevalence of HIV, HCV, and HBV amongst the potential donor population.⁸⁴ Lastly, the guideline points out the quantitative deficiency associated with simply labeling an organ “increased risk or non-increased risk” and proposes that a numerical “risk index” be developed to help patients gauge the actual threat of infection from a high risk organ associated with a behavior.⁸⁵ Such endeavors by the transplant community will go a long way in discerning what information is medically relevant in disclosure and evaluation policies.

Policy 4.0-Identification of Transmissible Diseases in Organ Recipients

The OPTN addresses the minimum requirements for divulging increased risk organ status and obtaining informed consent to the organ through *Policy 4.2-Requirements for Informed Consent Regarding risk of Transmissible Diseases*.⁸⁶ The language of the policy indicates that, “transplant programs must obtain informed consent prior to transplant of an organ when, in the transplant program’s medical judgment”, the donor:

- *Has a known medical condition which may be transmittable to the recipient,*
AND/ OR;

⁸³ *Id.* at 256 (this section of the material is devoted to making recommendations going forward and the immediate cite refers to recommendation number two).

⁸⁴ *Id.* at 256, 257 (referring to the fifth recommendation).

⁸⁵ *Id.* at 257, 258 (referring to the sixteenth recommendation made).

⁸⁶ ORGAN PROCUREMENT TRANSPLANT NETWORK, *supra* note 2.

- *The donor has been recognized increased risk for disease transmission*
*(including, but not limited to, those specified in the PHS Guideline...)*⁸⁷

The OPTN provides a list of those transmittable diseases which must be tested for prior to a living kidney transplantation.⁸⁸ Where the transplant team has decided, in their medical judgment, that the tests reveal a risk that they feel requires the informed consent of the recipient, it will disclose the issue to the patient.⁸⁹ In regards to risk behaviors, it is made clear in the PHS Guidelines that no quantitative value is attached to a risk behavior and its likelihood of transmission, rather, a qualitative indicia of “increased risk, or not increased risk” is all that is offered.⁹⁰

Recipients are also informed that it is impossible to comprehensibly screen for all transmissible diseases or remove all risk of obtaining an infection after transplantation.⁹¹ Those recipients that do receive increased risk organs must have their consent documented.⁹² Additionally, a strict post-operative care plan is offered to recipients of high risk organs so the hospital can monitor infections which may occur.⁹³ It seems, through this process, all medically relevant information is imparted onto the recipient so that a fully informed decision can be made. It is not required anywhere in this policy that risk behaviors be disclosed.

⁸⁷ *Id.*

⁸⁸ ORGAN PROCUREMENT TRANSPLANT NETWORK, *supra* note 62, at 185-188 (test for Requirements for living kidney donor medical evaluations).

⁸⁹ ORGAN PROCUREMENT TRANSPLANT NETWORK, *supra* note 2.

⁹⁰ See Kuehnert, *supra* note 1, at 257-258.

⁹¹ ORGAN PROCUREMENT TRANSPLANT NETWORK, *supra* note 2, POLICY 4.2.3, at 4-1 to 4-2.

⁹² *Id.* see POLICY 4.2.1, at 4-1.

⁹³ *Id.* see POLICY 4.2.2, at 4-1.

Part III- CMS and Organ Transplantation Oversight

The Center for Medicaid and Medicare Services distinguishes its role from the OPTN by stating it is responsible for the oversight and compliance of the transplant community, whereas the OPTN serves to promote the equitable and efficient allocation of the organ supply.⁹⁴ In part, the objective of CMS oversight is to address minimum standards of acceptable performance amongst transplant programs.⁹⁵ CMS seeks to create expectations of performance and high quality transplant services through comparable performance measurements.⁹⁶ In 2007, CMS promulgated conditions of participation (CoPs) for those transplant programs participating in Medicare and, thus, required transplant centers across the country to abide by the terms of the CMS regulations in order to obtain approval, or re-approval, of their respective institutions.⁹⁷ As part of the conditions of participation, CMS set forth a section devoted to patient and living donor rights.⁹⁸ The section provided that each transplant entity ensure the protection and promotion of the rights of both parties to a transplantation.⁹⁹

The Rights afforded Recipients through CMS Regulation: Informed Consent

In an effort to protect the rights of the transplant recipient, CMS issued its own rules as to the minimum criteria necessary to achieve fully informed consent.¹⁰⁰ The rules require that transplant centers institute their own written policies of the informed consent process.¹⁰¹ Most

⁹⁴ See CENTER FOR MEDICAID AND MEDICARE SERVICES, U.S. DEP'T OF HEALTH AND HUMAN SERV., HEALTH RESOURCES AND SERVICES ADMINISTRATION, FINAL RULE: 42 C.F.R. 405, 482, 488, at 15198, 15198-15160 (2007) (CMS explaining the role it will play in the oversight and regulation of the transplant community).

⁹⁵ 42 C.F.R. §482.80(c) (2012); See *id.*

⁹⁶ *Id.*

⁹⁷ 42 C.F.R. §482.

⁹⁸ 42 C.F.R. §482.102

⁹⁹ *Id.*; 42 C.F.R. §482.13.

¹⁰⁰ 42 C.F.R. §482.102(a).

¹⁰¹ *Id.*

notably, in order for the transplant center's informed consent policy to comply with CMS regulations, it obligates the entity to inform the candidate as to: the evaluation process, the surgical procedure, potential medical and psychosocial risks, organ donor risk factors that could affect the graft or health of the patient, and his or her right to refuse the treatment.¹⁰² CMS qualifies "donor risk factors" to include, but not limit, informing the patient of, "the donor's history, condition or age of the organ used, and the patient's potential risk of contracting HIV or other infectious diseases if the disease cannot be detected in an infected donor."¹⁰³ "Donor history" is a term, however, that remains undefined. It could refer to donor's relevant medical history, any significant family medical history, or the donor's social behavioral history. This leaves the term open for interpretation by the transplant program.

The CMS regulations do not expressly distinguish between recipients of living donor high risk organs from those that receive high risk organs from deceased donors.¹⁰⁴ Therefore, it could be presumed that the patients' rights in the informed consent process and the information that are entitled to receive are the same in both types of transplants.¹⁰⁵ Additionally, there is no rule limiting the transplant hospital's ability to disclose other risk factors, outside of those stated in the CMS regulation, that the medical team finds are significant to the patient in making their decision.¹⁰⁶ The CMS regulations dictate that the determination of what donor risk factors that should be disclosed to a recipient ought be left to the transplant surgeon, but that, at a minimum, all factors addressed in §482.102(a) should be discussed.¹⁰⁷

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *See*, Kuehnert, *supra* note 3, at 2570.

¹⁰⁵ *Id.*

¹⁰⁶ 42 C.F.R. §482.102(a)(6).

¹⁰⁷ *See* CENTER FOR MEDICARE AND MEDICAID SERV., *supra* note 93, at 15240.

CMS and Donors: Privacy Protections

The CMS protections afforded donor privacy in the living donor context are stated rather briefly in the regulations. Initial protection of patient privacy is provided in the conditions of participation which mandate that the patient maintain his right to personal privacy throughout the care process and that the clinical records of the patient be kept confidential.¹⁰⁸ CMS adds further protections for patients through its living donor consent requirements which obligate the transplant centers to inform the donor that all communications between the donor and the transplant center are “to remain confidential, and in accordance with the requirements proscribed under 45 CFR Parts 160 and 164”.¹⁰⁹ The CFR provisions referenced in this rule are better known as The HIPAA Privacy Rule.¹¹⁰

CMS and Protections Afforded under The HIPAA Privacy Rule

The terms of The HIPAA Privacy Rule dictate which disclosures of protected health information (PHI) require authorization and consent directly from the patient and which uses do not necessitate such written or oral permission.¹¹¹ While organ procurement organizations fall outside of the control of these disclosure limitations, transplant hospitals are subjected to the provisions of the law.¹¹² The sections of the HIPPA Privacy Rule discussed here illustrate the legal requirements covered entities have in protecting PHI, instances where covered entities are permitted to use PHI for particular purposes, and circumstances where authorization for disclosure is not required at all.

¹⁰⁸ 42 C.F.R. §482.13(c)(1); *Id.* §(d)(1).

¹⁰⁹ 42 C.F.R. §482.102(b).

¹¹⁰ 45 C.F.R. §§160, 164 (2002).

¹¹¹ CENTER FOR MEDICAID AND MEDICARE SERV., U.S. DEP'T OF HEALTH AND HUMAN SERV., HUMAN RESOURCES SERV. ADMIN., FINAL RULE: 45 C.F.R. §§160, 164, at 53182, 53182-183 (2002).

¹¹² 45 C.F.R. §164.214(h).

The Privacy Rule requires all covered entities to advise patients of the legal duties the entity has in regards to keeping all PHI confidential.¹¹³ Where a particular treatment is being offered, the hospital must give adequate notice to the patient of the uses and disclosures of protected health information that may be made by the hospital in the course of that treatment.¹¹⁴ The hospital must also advise the patient of his legal rights in regards to such information, which include: unrestrained access to his protected health information, the right to protest a disclosure, and access to a record that accounts for all disclosures of patient PHI.¹¹⁵ The notice must be written out in plain language for the patient and include examples of the types of disclosures which may occur.¹¹⁶ Patients retain the right to object to disclosures prior to treatment through entering into legally binding agreements with the hospital restricting the use of the information.¹¹⁷ However, the hospital does not have to agree to enter the restriction agreement simply because the patient disagrees with the disclosure.¹¹⁸

A hospital is permitted to use the PHI of a patient for the purposes of carrying out: treatment, payment, and healthcare operations.¹¹⁹ Hospitals do not have to obtain consent from the patient in using PHI where it concerns performing these functions of his care.¹²⁰ However, the covered entity is limited to disclosing PHI to only those parties that are necessary to carry out the treatment of *that* patient.¹²¹ For instance, where the treatment of a third-party patient is concerned, another patient's PHI is not permitted to be disclosed under this provision to aid in

¹¹³ 45 C.F.R. §164.520.

¹¹⁴ *Id.* §(a)(1).

¹¹⁵ *Id.*

¹¹⁶ *Id.* §(b)(1); *Id.* §(b)(1)(ii)(A).

¹¹⁷ 45 C.F.R. 164.522(a)(1).

¹¹⁸ *Id.* §164.502(c).

¹¹⁹ *Id.* §164.506.

¹²⁰ *Id.*

¹²¹ *Id.*

the care of that third-party patient.¹²² It seems then that, in the context of a living donor transplant, where a hospital intends to use the PHI of the donor in obtaining the informed consent of the recipient, it must notify the donor of this intent, and must receive authorization and consent from the him to do so.

Possible Loopholes for Unauthorized Disclosures for Transplant Hospitals in HIPAA

The Privacy Rule recognizes that health institutions must reveal certain medical information to particular entities and persons without having to receive the permission of the patient.¹²³ This allowance is granted when, for instance, a medical or health entity is required to report information for the purposes of research, reporting is necessary for the benefit of the public health, or to notify institutions of a significant health threat.¹²⁴ In the context of living transplantation, unauthorized disclosures will occur to satisfy OPTN reporting requirements, when the HHS or CMS makes a request for information, or when an infection occurs and those affected need to be notified.¹²⁵

Transplantation is specifically referenced within the Privacy Rule in regards to deceased organ donation.¹²⁶ It permits the use and disclosure of PHI by a covered entity to other transplant programs in the context of cadaveric organ, tissue, or eye donation and transplantation.¹²⁷ There is no rule within the permitted unauthorized disclosures section that allows revealing the PHI of a living organ donor to an organ recipient without consent from the

¹²² ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP'T FOR HEALTH AND HUMAN SERVICES, GUIDANCE FOR DONOR AND RECIPIENT INFORMATION SHARING 1, 4 (2012) (standing for proposition that information shared between donor and recipient in the living donor context requires HIPAA authorization), *available at* http://optn.transplant.hrsa.gov/ContentDocuments/Guidance_Information-Sharing_HIPAA_2012.pdf.

¹²³ 45 C.F.R. §164.510.

¹²⁴ *Id.*

¹²⁵ ORGAN PROCUREMENT TRANSPLANT NETWORK, *supra* note 122.

¹²⁶ 45 C.F.R. §164.512(h).

¹²⁷ *Id.*

donor. A transplant hospital could, perhaps, attempt to interpret the “threat to health” exception to allow an unauthorized disclosure of donor PHI because it permits unauthorized disclosures in order to avert a serious threat to health or safety.¹²⁸ In order to do so, however, a covered entity must make a good faith determination that disclosure is necessary to “prevent or lessen a serious and imminent threat to a person”.¹²⁹ It would be a far stretch for a transplant hospital to argue that the revelation of the risk behavior of an organ donor to the recipient falls under the exception. The legislation, likely, would have provided for an exception in the permitted unauthorized disclosures section to address the need to reveal the PHI of a living donor if it felt the circumstances required it.

Part IV-Informed Consent and the Common Law

Informed consent, at common law, provides a patient with a legal remedy where he has been harmed because he was left unaware by the physician of information which would have played a significant role in his medical decision-making process.¹³⁰ The common law development of informed consent has played a pivotal role in preventing patients from being left with inadequate information when making a medical decision.¹³¹ Particularly, the courts have found that the informed consent theory has come to illustrate and uphold the fiduciary relationship between the physician and the patient, and the duties owed by the physician in that relationship.¹³² Physicians are thus required to disclose to patients, prior to treatment, the risks

¹²⁸ *Id.* §164.512(l)(i)(A).

¹²⁹ *Id.*

¹³⁰ *Howard v. Univ. of Med. and Dentistry of New Jersey*, 172 N.J. 537, 546 (2002) (“[a] physician violates his duty to the patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.” (quoting *Largey v. Rothman*, 110 N.J. 204, 207-08 (1988))).

¹³¹ *Id.* (noting that the informed consent doctrine has continuously been refined to protect patients (citing *Natanson v. Kline*, 186 Kan. 393, 350 (1960))).

¹³² *Id.* (emphasizing the patient-centered approach to medicine, the right to self-determination, and the duty of the physician to meet this approach (citing *Canterbury v. Spence*, 464 F.2d 772, 786-88 (D.C.Cir.1972))).

associated with a particular type of treatment, the likelihood of such risks occurring, alternatives to the treatment, and any other medically relevant information that could affect the decision-making of the patient.¹³³

A physician has a duty to disclose to a patient information that will enable him to consider and weigh knowledgeably the options for medical treatment available and the risk attendant to each.¹³⁴ In some states, the approach is not what the reasonable patient would want to know, but rather, what the prudent physician would disclose as so the procedure.¹³⁵ This deviates from other views, such as New Jersey, which consider informed consent to be a patient centered concept. An action for breach of informed consent, in most states, is based upon failure to disclose a material risk of a proposed treatment that would compel a reasonable person in that patient's position to reject the treatment.¹³⁶ Where a patient/plaintiff is bringing an action for a physician's failure to obtain informed consent, the plaintiff must prove:

- 1. Doctor failed to give plaintiff all material information that a reasonable person in the plaintiff's position would expect a doctor to disclose so that plaintiff could make informed decision about course of treatment*
- 2. The undisclosed risk occurred*
- 3. A reasonable person under the circumstances of this case would not have consented to the treatment or operation had they been so informed AND*
- 4. The course of treatment or operation was a proximate cause in producing plaintiff's injuries or conditions*¹³⁷

¹³³ *Id.* at 548 (citing *Perna v. Pirozzi*, 92 N.J. 446, 459, 457 A.2d 431 (1983)).

¹³⁴ *Caputa v. Antiles*, 296 N.J. Super. 123, 133 (N.J. Super. Ct. App. Div. 1996) ("predicated on the duty of a physician to disclose to a patient such information as will enable the patient to make an evaluation of the nature of the treatment and of any attendant substantial risks, as well as of available options in the form of alternative therapies (quoting *Largey v. Rothman*, 110 N.J. 204, 208 (1988))).

¹³⁵ *Willis v. Bender*, 593 F.3d 1244, 1255-256 (10th Cir. 2010) ("Wyoming uses the reasonable professional standard").

¹³⁶ *Saks v. Ng*, 383 N.J. Super. 76, 92 (N.J. Super. Ct. App. Div. 2006) (the test for materiality is based upon whether a patient in the plaintiff's position would consider the risk material (citing *Matthies v. Mastro Monaco*, 160 N.J. 26, 36 (1999))).

¹³⁷ *Id.* at 94.

The elements listed above apply to those states that take the patient-centered approach to informed consent.¹³⁸ The determination of what information is to be disclosed to a patient is considered “not subjective as to either the physician or the patient, but rather, it remains *objective* with due regard for the patient's informational needs and with suitable leeway for the physician's situation.”¹³⁹ For instance, a patient highly susceptible to contracting a particular disease due to a personal immunodeficiency must be informed of that risk, whereas another patient may not face the same threat and thus, does not require the information because the threat is not material. Therefore, a risk cannot be presumed material and is instead a question left to the finders of fact.¹⁴⁰

It is not what that plaintiff would have decided if properly advised, but what a reasonably prudent person in the plaintiff's position would have decided if fully informed.¹⁴¹ A subjective characteristic of a patient, such as a bias against homosexuals, cannot be considered when determining whether information is material to the medical decision-making process.¹⁴² It beckons the court to ask whether or not knowing such information would have changed the decision of the reasonable patient and would the outcome had been different for the patient if the information had been disclosed.¹⁴³

In *Adamski v. Moss*, 271 NJ Super. 513 (N.J. Super. Ct. App. Div. 1994), the Court concluded that knowledge of a risk in the medical community could be established through the

¹³⁸ *Largey v. Rothom*, 110 N.J. 204, 212 (1988). (referencing support for choosing the prudent patient approach).

¹³⁹ *Id.* at 211 (quoting *Canterbury v. Spence*, 464 F.2d 772 (D.C.Cir.)).

¹⁴⁰ *Petrolia v. Estate of Nova* 284 N.J. Super. 585, 594 (N.J. Super. App. Div. 1995) (explaining that while the risk may have been material to the plaintiff/patient, it is for the jury to decide whether or not the undisclosed risk rose to the level of materiality).

¹⁴¹ *Skripek v. Bergamo* 200 N.J. Super. 620, 637 (N.J. Super. Ct. App. Div. 1985)

¹⁴² *Id.*

¹⁴³ *Id.*, quoted in, *Gordon v. Matez*, 2006 WL 3299180, at 4 (N.J. Super. Ct. App. Div. 2007).

defendant's expert or by use of medical literature.¹⁴⁴ This is a practical and substantial consideration when placed in the context of the informed donor recipient. It beckons the transplant community to determine whether knowledge of risk behaviors and their possible effects on transmission rates has been substantially accepted in the medical community and whether this knowledge impacts recipient outcomes.

Informed consent lawsuits have been brought against hospitals that were unable to detect an infection prior to the transplant.¹⁴⁵ The claim in *Baylor University Medical Center v. Biggs*, 237 S.W.3d 909 (Tex. App. 2007), was brought following an infection from a cadaveric organ.¹⁴⁶ The plaintiff was the recipient of an organ infected with rabies that died about a month after the transplant.¹⁴⁷ The plaintiff's estate argued that the transplant hospital, and its surgeons, failed to inform the decedent as to the high risk nature of the organ donor and, if they had, the decedent would have declined the organ.¹⁴⁸ The court evaluated the informed consent claim under the rules of the state which required the plaintiff to show the "undisclosed risk would have influenced a reasonable person in making a decision to consent to the procedure."¹⁴⁹ It found that while that informed consent claim could certainly be brought and upheld in these circumstances, the plaintiff's expert reports failed to establish the proper standard of care, the breach, and the causation which connecting the breach to the injury.¹⁵⁰ Specifically, the court pointed to shortcomings in establishing the proper procedure for informed consent in

¹⁴⁴ *Adamski v. Moss*, 271 NJ Super. 513, 517 (N.J. Super. Ct. App. Div 1994).

¹⁴⁵ *Baylor Univ. Med. Ctr. V. Biggs*, 237 S.W.3d 909 (Tex. App. 2007).

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 914.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* at 922, 923.

transplantation, whose duty it was to disclose the information, and whether it was possible to discern the status of the deceased donor at the time of the transplant.¹⁵¹

I am persuaded that the most appropriate application of informed consent in the medical context requires one to ask, “Would a reasonable patient find the information material in making a medical decision?” Materiality must be an objective measure in this case, and there is simply no support that any degree of certainty has been concluded in regards to the actual effects disclosing the risk behaviors of a donor has on infection transmission rates or successful transplantation.¹⁵² While certain patients may, in fact, change their minds upon learning of the risk behavior associated with the status of the organ, I do not believe the objectively reasonable, prudent patient would. The recipient is made aware of a risk, that being the possibility of transmission, for which the cause of has no effect on the impact or severity of that risk. The ethical considerations concerning the privacy of the donor and the legal protections afforded him, must, as a result, be paramount to the need to disclose.

Part V-Paired Exchange and Other Alternative to Risk Behavior Disclosure

All transplant candidates are permitted to enter and utilize the “Paired Exchange” program.¹⁵³ The Paired Exchange program is used when a transplant candidate has a willing donor, but that living donor is not a compatible kidney match with the recipient. Consider the following: Donor-Recipient Pair 1 have incompatible kidneys. Donor-Recipient Pair 2 is also incompatible. However, the Donor in Pair 1 is compatible with the Recipient in Pair 2. Likewise, the Donor in Pair 2 is compatible with the Recipient in Pair 1. The Paired Exchange program

¹⁵¹ Id.

¹⁵² Kuehnert, *supra* note 1, *passim*.

¹⁵³ ORGAN PROCUREMENT TRANSPLANT NETWORK, U.S. DEP’T OF HEALTH AND HUMAN SERV., POLICY 13.0-PAIRED KIDNEY DONATION (2013), *available at* http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_174.pdf.

will orchestrate a transplantation where the Donor in Pair 1 donates his organ to the Recipient in Pair 2, and the Donor in Pair 2 donates his organ to the Recipient in Pair 1.¹⁵⁴

This exchange could be completed while maintaining the confidentiality of any personally identifiable information of either of the donors as to the recipients. Where a donor is not willing to consent to having his risk behaviors disclosed to the known recipient, he should be offered the opportunity to place his organ on the Paired Exchange list where his personally identifiable information can be left confidential. Though the donor in our scenario is actually compatible, his reasons for being more comfortable with the paired exchange need not be revealed to the recipient.

Conclusion

This paper has presented and analyzed the transplantation process, the protections and rights afforded donors and recipients in it, and the legal sources for those rights and protections. It discussed the vagueness associated with many of the requirements placed upon transplant programs in following the rules and policies administered, and the broad interpretation allowances the overseeing agencies permit the programs to use when developing in-house protocol related to informed consent and privacy procedures.

The policy requirements thrust upon transplant programs through the Organ Procurement and Transplant Network and the Center for Medicare and Medicaid Services, I find, fully provide for the legal informed consent of the organ recipient. Furthermore, the expressed legal protections afforded donors under CMS regulations and through HIPAA do not permit such unauthorized revelations of protected medical information. There exists too little information,

¹⁵⁴ *Id.* (policy dictating the terms of the arrangement and the means of accomplishing it).

both quantitative and qualitative, to scientifically correlate risk behaviors to infections and their actual effect on transmission rates. While the CMS regulations call for the transplant programs to initiate discussions about donor history with the recipient, such a discussion can be limited to the risks posed by the donor's history without revealing personal privacy matters. It is essential that the ethical concerns of the donor be appropriately recognized and protected in this case.